REMARKS/ARGUMENTS

The pending claims are 1-43, 125-129, 140-145, and 201-212, and 331-336. New Claims 331-336 find support in Claims 201-212 and in the specification. No new matter has been entered.

The rejection under 35 U.S.C. 112 has been addressed. In particular, the specification has been amended to define the well known terms "Povidone K30" (polyvinylpyrrolidone), "Gelucire" (Gelucire compounds are hydrogenated fatty acid esters. The first two digits in the numeric portion of the Gelucire name represent the liquid/solid phase transition temperature in degrees centigrade and the second two digits represent the hydrophile/lipophile balance (HLB) value), and "Magnasweet 100" (ammonium glycirrhizinate). These definitions are found in U.S. patents 6,114,330, 6,613,353 and 5,849,322, respectively, all noted in the attached IDS. Intense Peppermint is simply a peppermint flavorant. Claim 27 has been amended to provide antecedent basis for the term "coating."

The term "5-Ht agonist" is defined at specification page 1, bottom, where "5-Ht" is noted as referring to 5-hydroxytryptamine. The term "spheronization aid" is defined at specification page 13, paragraph [0064], and the term "solubility enhancer" is defined at specification page 14, paragraph [0065]. Accordingly, the rejection under 35 U.S.C. 112 should be withdrawn.

The rejection over Ahlgren in view of "current drug formulation/preparation techniques" is traversed. In the first instance, it appears that the Examiner is taking Official Notice of certain "current drug formulation/preparation techniques" alleged to be in the prior art (see the sentence bridging pages 5-6 of the Official Action). Applicants contest this improper taking of Official Notice, and here present a seasonable challenge as the Examiner has completely omitted a basis for her reasoning: she has failed to provide specific factual

findings predicated on sound technical and scientific reasoning to support her conclusion of common knowledge. See MPEP 2144.03. In this regard, the Examiner has failed to show that it is routine or old in the art to add spheronization agents, solubility enhancers, coating materials, and sweeteners to a known active agent and to then optimize their ratios depending on the route of drug administration and the release profile required. In addition, it is incorrect to simply summarily conclude that for any known active ingredient all of its future formulations are unpatentable.

If the Examiner's taking of Official Notice amounts to nothing more than a general statement that different drug formulations containing the same active ingredient exist, it can be accepted. If it is anything more, Applicants demand that the Examiner produce authority for her statement in the form of documentary evidence and thereby show how one of ordinary skill in the art would have found it obvious to go from what is disclosed in Ahlgren to the present claimed invention.

Present claim 1 requires a rapid absorption pharmaceutical composition comprising an effective amount of at least one selective 5-HT (5-hydroxytryptamine ) agonist, at least one spheronization aid, and at least one solubility enhancer. Importantly, the specification at paragraph [0017] describes "rapid absorption" to mean a lower $T_{50}$ with an equal or higher $C_{max}$, of an oral dosage form of the invention when compared to a currently marketed oral triptan product, but having an area under the plasma-concentration time curve (AUC) that is equivalent to the currently marketed oral triptan product.[1] The AUC, or the Area Under the Curve, of the pharmacokinetic profile, signifies the extent of absorption of the drug. Thus, the presently claimed pharmaceutical composition is as effective as currently available compositions of 5-HT agonist, but quicker acting. This is no small feat, and to simply dismiss

[1] $C_{max}$ is the observed maximum plasma concentration and can be measured after a single-dose or steady state of the triptan for every dose given. Wagner-Nelson deconvolution defines $T_{50}$ as the time taken for 50% of the drug to be absorbed into the system.

this important advancement as obvious over Ahlgren in view of "current drug formulation/preparation techniques" is incorrect and improper.

Ahlgren discloses microspheres containing certain fatty acids, and for example discloses active agent sumatriptan at col. 4, line 65 in a true laundry list of active agents that may be used in the disclosed invention. However, nowhere in the reference, or in "current drug formulation/preparation techniques" is one of ordinary skill in the art directed to, or enabled to make, the presently claimed rapid absorption pharmaceutical composition comprising an effective amount of at least one selective 5-HT agonist, at least one spheronization aid, and at least one solubility enhancer. Nevertheless, the examiner simply concludes, without support, that it would have been obvious to one of ordinary skill to develop the presently claimed rapid absorption composition by starting with the composition of Ahlgren and then changing just about everything in it in order to provide the "fastest acting best tasting oral compositions . . .according to current drug formulation techniques" (see page 6 of the Official Action, 1st full paragraph).

Unstated in the rejection is the fact that the concept of a "rapid absorption" formulation came from Applicants' own disclosure. Moreover, and as pointed out above, the Examiner has failed to show that it is routine or old in the art to add at least one spheronization aid and at least one solubility enhancer and to produce a rapid absorption pharmaceutical composition as presently claimed, instead relying on a high level of skill in the art "evidenced" by an improper taking of Official Notice and the incorrect statement that it would have been obvious to provide the "fastest acting best tasting oral composition."[2] As noted in *In re Rouffet*, 47 USPQ2d 1453, 1458 (Fed Cir. 1998):

[2] For example, providing the "fastest acting" composition is not a general goal in the industry and ignores the entire class of controlled release pharmaceutical compositions.

> If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.

*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 82 USPQ2d 1385 (2007) did *not* alter this situation. While the KSR Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the Court acknowledged the importance of identifying "**a reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination.[3] Moreover, and as stated by the Federal Circuit in the post-KSR case *Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007) "in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." Of course, this same consideration - the requirement that the Examiner identify some reason that would have led a chemist to modify a known composition in a particular manner to establish prima facie obviousness - applies to new chemical compositions, such as Applicants' presently claimed rapid absorption pharmaceutical composition.

[3] KSR, 127 S. Ct. at 1731. Emphasis added.

Accordingly, and because the rejection fails to present a *prima facie* case, and because improper Official Notice has been taken, Applicants respectfully request the withdrawal of the outstanding rejection and the passage of this case to Issue.

Respectfully submitted,

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